K120642

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510(k) Summary
acc. to 807.92

NOV 2 2012

Manufacturer Name and Address: Dräger Medical Systems, Inc.
3135 Quarry Road
Telford, PA 18969

Establishment Registration Number: 2510954

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Date summary was prepared: 2012-10-04

Device Name:

Trade Name:	Resuscitaire Radiant Warmer
Classification Name:	Infant Radiant Warmer
Regulation Number:	21 CRF 880.5130
Product Code:	FMT
Class:	II

Legally Marketed Device Identification: Substantial equivalence is claimed to the Resuscitaire® Radiant Warmer K003335, Neopuff Infant Resuscitator K892885, and MVP-10 Infant Ventilator (MVP10) K89638.

Device Description:

The modified Resuscitaire Radiant Warmer is for newborn infants and consists of a bassinet, warmer and a controller module which provides heat control, monitoring of the skin temperature and an APGAR timer. It also includes optional manual and automated resuscitation with suction and oxygen delivery and a patient gas supply breathing circuit.

Intended Use:

The Resuscitaire Radiant Warmer is intended for thermoregulation, skin temperature monitoring, APGAR timing and resuscitation of newly born infants up to 10kg. It is not intended for long term resuscitation or home use.

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Comparison of Technological Characteristics with Predicate Devices:

Specification	Predicate	Predicate	Predicate	Device Under Review	Comments
Device Name	**Resuscitaire® Radiant Warmer**	**MVP-10K1Ventilator (MVP10) Predicate for AutoBreath Feature Only**	**Neopuff Infant Resuscitator Predicate for AutoBreath Feature Only**	**Resuscitaire® Radiant Warmer**	
Manufacturer	Hill-Rom Air Shields	Bio-Med Devices Inc.	Fisher & Paykel	Draeger Medical Systems, Inc.	
510(k) Number	K003335	K896381	K892885		
Regulation Number	880.5130	868.5895	868.5925	880.5130	
Product Code	FMT	CBK	BTL	FMT	
Classification	II	II	II	II	
Intended Use	Intended for thermoregulation, skin temperature monitoring, APGAR timing and resuscitation of newborn infants in the labor and delivery room.	Intended for respiratory support of neonatal and pediatric patients both in hospital and during transport. Primarily for use in applications requiring tidal volume up to 660 ml. May be used with a wide range of I:E ratios including inverse ratios.	Intended for resuscitation of infants in labor & delivery, postnatal wards, ORs, transport, special care baby units, and NICUs	Thermoregulation, skin temperature monitoring, APGAR timing and resuscitation of newborn infants. It is not intended for home use or long-term resuscitation	The Intended Use has been modified to clarify the use of the device with or without the AutoBreath option.
Indications for Use	Thermoregulation, skin temperature monitoring, APGAR timing and resuscitation of newborn infants.	Not Found on FDA Site	Not Found on FDA Site	Thermoregulation, skin temperature monitoring, APGAR timing and resuscitation of newly born infants up to 10 kg. It is not intended for long-term resuscitation or home use.	The Indications have been modified to clarify the use of the device with or without the AutoBreath option.
Target Population/Patient Population	Newborn infants	Newborn and Pediatrics	Newborns and Pediatrics	Newly born infants up to 10 kg.	The 10 kg is in reference to the weight the Resuscitaire Radiant Warmer bed is made to hold.
Environment of Use	Labor and delivery room in a Healthcare Facility			Labor and delivery setting in a Healthcare Facility	
AutoBreath™ Infant Resuscitator Feature (AB)					

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Operating Principle	N/A	Gas powered, continuous flow, time cycled BPM, pneumatically driven logic circuit	Gas powered, continuous flow, manually cycled BPM	Same as Predicate MVP-10	
I:E Ratio	N/A	1:8 to 3:1 (adjustable)	Manually estimated	Fixed internally at 1:2 nominal (1:1.6 to 1:2.2) (non adjustable)	The fixed I:E ratio of the AB falls within the normal range for neonatal ventilation as published in the. Assisted Ventilation of the Neonate 4th Edition copyright 2003, (1:1 to 1:3). Additionally the 2010 AHA Guidelines for neonatal resuscitation recommend breath rates of 40 -60 BPM. All three devices can provide I:E ratios within the recommended range The Neopuff is manually estimated and controlled by the user therefore both the I:E ratio and BPM will vary. The preset I:E ratio of the RW82 w/ AB eliminates human variation by guaranteeing a consistent I:E ratio. The MVP-10 incorporates a wider range of I:E

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					ratios including inversion ratios for use outside L&D and with larger patients. The RW82 w/AB is only used for clinician administered short term resuscitation in L&D settings.
Adjustable PEEP	N/A	Variable up to 18 ± 3 cm H2O at a flow of 6 l/min	@ 5 LPM 1-5 cm H20/mbar @ 8 LPM 1-9 cm H20/mbar @ 10 LPM 2-15 cm H20/mbar @ 15 LPM 3-25 cm H20/mbar	@ 5 LPM minimum PEEP <2 cm H2O @ 10 LPM minimum PEEP ≤ 4 cm H2O @15 LPM maximum PEEP > 14 cm H2O	Although not identical, the PEEP ranges are similar. Based on the application of use the differences are not significant. For newborns the recommendations are: minimum PEEP from 3 to 4 cmH2O, and flow rate 5 to 8 LPM for low birth weight infants and flow rate 6 to 10 LPM for term infants
Adjustable Respiratory Rate Range	Achieved via bag and mask resuscitation, user dependant	Variable from 0 to 120 BPM	Achieved via t-piece breathing circuit, user dependant	18 to 60 BPM ± 10% of setting	Both the RW82 w/ AB and the MVP10 allow the user to set the respiratory rate. The advantage of a set respiratory rate is to eliminate the human variation associated with manually controlled rates (RW82 & Neopuff). The MVP10 has a larger respiratory rate range. This larger range

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					is due to the patient population of the MVP10 which includes pediatrics. The RW82 w/ AB is only intended for the resuscitation of newborns in L&D environments.
Adjustable Airway Pressure Relief (range of working pressure) (PIP)	None	10 cm H20 ± 5 to 80 cm H2O ± 10	2 to 80 cm H2O	0 to 50 cmH2O ± 5 cm H2O (0 to 4.9 kPa ± 0.5 kPa)	The MVP10 and the Neopuff have a larger range based on patient populations for ventilation, while RW82 w/ AB is only intended for the resuscitation of newborns in L&D environments.
Fixed Max Pressure (P Lim min)	160 cm H2O (15.7 kPa) ± 10%	Variable up to 70 cm H2O ± 10	Variable up to 80 cm H2O	50 cm H2O ± 10% (5.0 kPa ± 10%)	The differences between the fixed max pressures of the MVP-10, Neopuff & Auto-Breath are related to the environment in which resuscitation is provided. The Neopuff uses a T-piece circuit with manually adjustable PEEP & PIP with higher fixed max. pressure for use in the NICU. Like the Neopuff, the RW82 w/ AB also provides manually adjustable PEEP & PIP. It differs in that it provides a lower fixed max. pressure because the

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					intended use is limited to the L&D. The RW82 is not a predicate for this function.
Fixed Min Pressure (P Lim min)	0 cmH2O	0 cmH2O	0 cm H20 ±2	Same as predicate RW82	
Logic Circuit	None	Approx 4 LPM at 50 BPM	None	5 LPM	Like the MVP-10 the RW82 w/ AB is a pneumatically controlled device. Both circuits control the time intervals between exhalation and inspiration and the pressure in the patient circuit.
Dead Space	N/A	0.5 ml max	6 ml	3.4 ml	Dead space will vary based on the make up/mfg. of the patient breathing circuit.
Body Weight Range	N/A	Applications requiring TV up 660 mls.	Up to 10 kg	Same as Neopuff	
Patient Interface	N/A	Endotracheal Tube	Face Mask or Endotracheal Tube	Face Mask	
Infant Resuscitator Feature					
Patient Gas Supply Airway Pressure Limit, Operator Adjustable	0 to 50 cm H2O (0 to 4.9 kPa) ± 10% of max setting	N/A	N/A	Same as predicate RW82	
Patient Outlet Flow Control Range	0 to 15 LPM ± 3% of full scale or ± 10% of setting, whichever is greater	N/A	N/A	Same as predicate RW82	
Fixed Airway Pressure Limit, Preset	60 cm H2O (4.9 kPa) ± 20 % of setting	N/A	N/A	Same as predicate RW82	
Auxiliary Supply Pressure Limit	160 cm H2O (15.7 kPa) ± 10% of setting	N/A	N/A	Same as predicate RW82	

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Auxiliary Flow Control Range	0 to 15 LPM ± 3% of full scale or ± 10 % of setting whichever is greater	N/A	N/A	Same as predicate RW82	

Discussion of Non-clinical Studies:

The modification of the RW82 to include AutoBreath was tested in accordance with applicable standards, guidance and internal design control procedures including performance testing, functional/operation testing, verification and validation, biocompatibility, risk analysis and verification of risk control measures and was determined to be as safe and effective for its intended use as the predicates. Testing performed indicate that the modifications as described in this submission have not altered the fundamental application of the device in its intended environment.

Biocompatibility:

Testing was performed to ISO 10993. The results show the relevant components to be biocompatible.

Sterilization:

Not applicable

Standards and Guidance:

Performance Standards:

None

International Standards:

ISO 5356-1 Anaesthetic and respiratory equipment – Conical connectors – Part 1: Cones and sockets

ISO 10651-5:2006 – Lung ventilators for medical use – Particular requirements for basic safety and essential performance – Part 5

AAMI/ANSI/ISO 10993-1:2009, Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process

AAMI/ANSI/ISO 10993-1:2009, Biological evaluation of medical devices – Part 5, Tests for in vitro Cytotoxicity

AAMI/ANSI/ISO 10993-1:2009, Biological evaluation of medical devices – Part 10, Tests for irritation and delayed hypersensitivity

AAMI/ANSI/ISO 10993-1:2009, Biological evaluation of medical devices – Part 12, Sample preparation and reference materials

ISO 5356-1 Anaesthetic and respiratory equipment – Conical connectors – Part 1: Cones and sockets

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Guidance:
Draft Emergency Resuscitator Guidance, April 1993
Draft Reviewer Guidance for Ventilators, July 1995

Conclusion Drawn from Non-Clinical Studies:

The results of the non-clinical testing, and comparison to the predicate devices show that the modified Resuscitaire Radiant Warmer meets the performance requirements of the standards and guidance mentioned above and is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center -- WO66-G609
Silver Spring, MD 20993-002

Dräger Medical Systems, Incorporated
Ms. Gale Winarsky
Manager, Regulatory Affairs
3135 Quarry Road
Telford, Pennsylvania 18969

November 2, 2012

Re: K120642
Trade/Device Name: Resuscitaire Radiant Warmer
Regulation Number: 21 CFR 880.5130
Regulation Name: Infant Radiant Warmer
Regulatory Class: II
Product Code: FMT
Dated: October 5, 2012
Received: October 9, 2012

Dear Ms. Winarsky:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Digitally signed by Anthony D. Watson
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Anthony D. Watson, 0.9.2342.19200300.100.1.1=1300092402
Date: 2012.11.02 12:55:46 -04'00'

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
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Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K120642

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Indications For Use:

The Resuscitaire® Radiant Warmer is intended for thermoregulation, skin temperature monitoring, APGAR timing and resuscitation of newly born infants up to 10kg. It is not intended for long term resuscitation or home use.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

11/2/12

K120642

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K120642